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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,323	09/20/2005	Richard M. Simonson	GWK-101-US	5343

7590 08/03/2010

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,323	SIMONSON ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2010 has been entered.

Claims 1 and 6-8 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanbrom U.S. Patent No. 5,811,471 A.

Shanbrom teaches antimicrobial dye such as gentian violet (see abstract, column 4, lines 27-30 (crystal violet is synonymous with gentian violet), column 4, lines 4—51, see claim 2) employed in germicidal absorptive material such as polyurethane foam which Shanbrom teaches is effective at binding the dyes (column 4, lines 53-60). The antibacterial activities of these germicidal dyes are well known in the art and disclosed in Shanbrom. Shanbrom further teach that glycerin is employed in treatment solutions with as much as 50% and also teach 1-2% (column 3, lines 34-47). This range encompasses the claimed range of about 6%[1] glycerin. Shanbrom teaches the advantages of employing glycerin, including solubilizing the disinfectant dye and to maintain softness of the sponge and to improve future water uptake when the material is dried (column 3, lines 34-47). The step of drying the sponge to remove the unbound

dye is recited (see claim 1). Shanbrom teaches a concentration of 4 mg/ml whereas the instant claims are drawn to an unknown amount of gentian violet ranging from 1-3% (instant claims 1 and 7) and 8 drops of gentian violet 1% in a volume of 480 ml of water. or 6-10 drops of 1-3% solution. If the gentian violet solution is equivalent to the volume of a water drop, then 60 drops = 1 fluid dram or 30 ml. If 10 drops of a 3% solution is employed, then this would be equivalent to 1/6th of an ounce or 5 ml. 3% = 30g/100ml or 30 mg/ml. Thus 150 mg is dispersed in 480ml of solution. 150mg/480ml = 0.31 mg/ml. This is hypothetical since the volume of a drop can vary depending on the density, temperature, viscosity, surface tension and the shape and nature of the surface from which it is dropped. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While it is unclear whether the amount of gentian violet overlaps with the amount recited in the reference, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious. Addressing instant claim 7, drawn to a sponge with bound dye and a transparent backing film bonded to the sponge with pressure sensitive adhesive with water-impervious polyethylene for “bedsore” sheeting, Shanbrom teaches disinfectant

[1] About 30 cc / about 450 cc = about 6.7%

dyes such as gentian violet bound to a PVA substrate such as simple bandages, or cleansing wipe. It does not teach water-impervious polyethylene, however, since Shanbrom teaches bandages, it would have been obvious to employ a water impervious back motivated by the teaching of Shanbrom that the composition is employed on bandages. Furthermore, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. Se *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Addressing instant claim 8 whereby undesirable staining of the skin, dressings, sheets and clothes is reduced or avoided during use of said pad, Shanbrom teaches that the germicidal material is not released from the absorbent material so that it does not irritate the surrounding tissues (column 2, lines 19-21). Further, Shanbrom recommends that even though dyed PVA material appears non-irritating, it recommends that a thin surface layer of undyed PVA or some other permeable material be employed to prevent direct contact between human tissues and the dyed material. The comprising language of the instant claims does not exclude the such a film or layer.

No claims are allowed.

Response to Arguments

In response to applicant's argument drawn to the lack of "tattooing of the skin" in an ulcerative lesion, Shanbrom teaches that the germicidal material is not released from the absorbent material so that it does not irritate the surrounding tissues (column 2,

lines 19-21). In response to Applicant's assertion that "the Gentian Violet must be used in the correct volumes so as to not impede adsorption of exudate, or in other words, once the pad is dried, by eliminating the water, there is adequate volume in the sponge to absorb exudate." Shanbrom teaches the step of drying the sponge to remove the unbound dye is recited (see claim 1). And further teaches that a trace of glycerin left in the PVA (sponge/pad) can help maintain softness and improve future water uptake when the material is dried (column 3, lines 42-47). The improvement of future water uptake would be inclusive of watery exudate from a wound.

Applicant states that comparable claims are in the process of being allowed by the European Patent Office in a corresponding application and recommends that the Examiner use the "Patent Highway procedure". In response, the application number has not been identified to the United States Patent Office. The relatedness of claims and the process cannot be determined. Applicant is reminded of the duty to disclose information material to patentability including prior art cited in search reports of a foreign patent office in a counterpart application. See MPEP § 1.56.

Applicant's further arguments with respect to claims 1 and 6-8 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

July 28, 2010